US MS

WORKSHOP ANNOUNCEMENT

National Institute of Standards and Technology

Imaging as a Biomarker: Standards for Change Measurements in Therapy

14–15 September 2006, NIST, Gaithersburg, Maryland

A U.S. Measurement System (USMS) Workshop

Imaging as a biomarker of drug response is becoming an increasingly important field of research. The Food and Drug Administration (FDA), the National Cancer Institute (NCI), and the Centers for Medicare and Medicaid Services (CMS) have agreed to collaborate on improving the development of cancer therapies and outcomes for cancer patients through biomarker development and evaluation <http://www.fda.gov/oc/mous/domestic/FDA-NCI-CMS.html>. A similar effort across the National Institutes of Health's (NIH's) Institutes and Centers (ICs) is being planned. Biomarkers are biological indicators of disease or therapeutic effects that can be measured by *in vivo* biomedical imaging and molecular imaging in particular, as well as other *in vitro* or laboratory methods. Recent work has shown that biomedical imaging can provide an early indication of drug response by use of X-ray, CT or PET-CT.

Many sources of uncertainty exist in imaging as a biomarker. Biological variability, for example, is a factor that is both drug- and patient-dependent and thus difficult to characterize or model. However, other uncertainties are associated with the image data collection platform and the robustness of software tools required for reliable, quantitative measurement of change over time, such as tumor volume, radioactive tracer activity, or contrast agent dynamics. All these sources of uncertainty significantly affect the statistical power of clinical drug or therapy trials. Measurement of change over time with imaging for a variety of disease models will be presented.

The development of standards for image quality control, image data collection, and benchmarking of change analysis software tools, as well as image-specific statistical methods, could significantly reduce the size of clinical trials for drug response. The cost of drug development and submission to the FDA by the pharmaceutical industry may soon exceed $1 billion. Standardized imaging methods may reduce these costs.

The scope of this workshop is focused on the need to standardize imaging methods for data collection and data analysis in the context of drug or radiation therapy trials. Topics for breakout discussions include:

- Instrument quality control over the time sequence of a trial (modalities include: X-Ray, X-Ray CT, PET, PET CT, MRI, MRS, DCE and Diffusion MRI. Emerging modalities will also be discussed)
- Harmonization of data collection across different commercial imaging platforms
- Creation of standardized, objective performance metrics for image-analysis software using reference image databases or test beds
- Standardized statistical methods for change measurement
- Archival and access methods for image storage, related meta-data, and clinical outcome data
- Innovative methodologies for the integration of image and other data for clinical decision making

Workshop participants should address the following questions with respect to the above topics:

- What technological innovations are at stake?
- What is the economic significance of the innovations?
- What technical barriers to the innovations impede progress to the marketplace?
- At what stages of innovation (R&D, Production, Marketplace, End Use) do the technical barriers appear?
- What parts of the technical barriers are measurement science or standards development?
- What are the potential solutions to the measurement and standards development problems?
- Who are potential providers of solutions?
- Are there critical roles for agencies of the federal government?

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Updated workshop agenda and registration links are available under "workshops" on
the NIST U.S. Measurement System website <http://usms.nist.gov>

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